

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON

SMITH & NEPHEW, INC. and JOHN O.
HAYHURST, M.D.,

Plaintiffs,

v.

ARTHREX, INC.,

Defendant.

No. CV 04-29-MO

OPINION & ORDER
RE: SUMMARY JUDGMENT

MOSMAN, J.,

In this case, Smith & Nephew¹ alleges Arthrex has four devices that infringe its 5,601,557 ("557") patent. The parties filed cross motions for summary judgment raising a variety of issues, including infringement and the validity of '557. A hearing was held addressing these motions on February 26, 2007. At that time, I denied Smith & Nephew's motion on infringement and granted its motion as to inequitable conduct. Arthrex's motion and the remaining issues raised in Smith & Nephew's motion were taken under advisement. On March 1, 2007, I issued a supplemental minute order granting Arthrex's motion on non-infringement as relates to the

¹For ease of reference, the plaintiffs are referred to collectively as "Smith & Nephew."

V-Tak device, but denying its motion as to its other three accused devices. I also denied Arthrex's motion on validity as relates to the *Perthes* prior art, and granted Smith & Nephew's motion on validity as relates to the *McLaughlin*, Screw-as-Post Technique, *Augustine*, and *Somers* prior art references. All other issues remained under advisement. This opinion follows to explain the reasoning of my prior rulings and resolve the undecided issues. As the parties are familiar with the background of this case, it is not set out here, except as is necessary in the discussion below.

I.) Summary Judgment Standard

Summary judgment is appropriate where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the initial burden of "pointing out" the absence of a genuine issue of fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). This burden is met by showing an absence of evidence to support the non-movant's case. *Id.* In order to defeat summary judgment, the non-moving party must then set forth "specific facts showing there is a genuine issue for trial." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (quoting Fed. R. Civ. P. 56(e)). The court views the record in a light most favorable to the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no genuine issue for trial." *Id.* (citation omitted).

II.) Infringement

Infringement is a two-step analysis. First, the meaning and scope of the patent claims must be determined. *AquaTex Indus., Inc. v. Techniche Solutions*, 419 F.3d 1374, 1380 (Fed. Cir. 2005). Second, the claims are compared to the accused device or methodology. *Id.* Direct infringement can be shown two ways: (1) literal infringement; and (2) infringement through equivalency. *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1350-51 (Fed. Cir. 1999).

Literal infringement is where "the accused device contains every limitation in the asserted claims. If even one limitation is missing or not met as claimed, there is no literal infringement." *Id.* at 1350. Under the doctrine of equivalency, infringement also occurs where "the accused product contain[s] each limitation of the claim or its equivalent." *AquaTex Indus., Inc.*, 419 F.3d at 1382. This standard is met when the accused device "performs substantially the same overall function or work, in substantially the same way, to produce substantially the same overall result as the claimed invention." *Dolly, Inc. v. Spalding & Evenflo Co.*, 16 F.3d 394, 397 (Fed. Cir. 1994) (citing *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950)) (further citations omitted). Collectively, this is referred to as the "all limitations" rule. *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1358 (Fed. Cir. 2005). Unlike claim construction, infringement is a question of fact, generally reserved for the jury. *Catalina Lighting, Inc. v. Lamps Plus, Inc.*, 295 F.3d 1277, 1285 (Fed. Cir. 2002).

A.) Smith & Nephew's Motion

Smith & Nephew argues it is entitled to summary judgment on infringement as relates to all four of Arthrex's accused devices. As stated at the hearing in February, Smith & Nephew's motion is denied. In relation to a multi-claim patent, like the one at issue here, infringement is established where the accused device is shown to embody all of the limitations of any one of the patent's claims. *Intervet Am., Inc. v. Kee-Vet Labs., Inc.*, 887 F.2d 1050, 1055 (Fed. Cir. 1989) ("A patent is infringed if a single claim is infringed."). Here, Smith & Nephew cannot show for purposes of summary judgment that Arthrex's devices are "members," as required by each of '557's claims.

In *Smith & Nephew v. Ethicon*, No. CV 98-76-MA (D. Or. June 11, 1999),² Magistrate Judge Hubel construed "member" as "the anchor itself." He further held this term requires "that the entire member is resilient." As set out in an earlier opinion, Judge Hubel's construction

²Hereafter, Judge Hubel's opinion in *Ethicon* is referred to as "Hubel's Am. F&R."

applies here under principles of claim preclusion. Judge Hubel did not, however, define "resilient," and the parties now dispute the import of this term.

At the February hearing in this case, I construed "resile," a term appearing solely in claim two, as follows: "'Resile' means to return to or tend to return to a prior or original position in a manner that contributes, at least in part, to the lodging of the member in the hole. Completely returning to a prior or original position, though included, is not required." Though occurring after Judge Hubel's claim construction, my construction necessarily relates to his. Thus, the issue concerns the proper relationship or relative meanings of "resile" and "resilient."

Given the context, "resile" as used in claim two clearly refers to the act of resiling or a device resiling in use.³ Judge Hubel's intended meaning of "resilience" is less clear, but it appears there are two possible meanings. First, it is used as a synonym for "resile," requiring that the device actually perform in a resilient manner in order to meet the definition of "member." This is a resilient-in-use interpretation. The second possibility is that Judge Hubel meant that the device must simply have the *capacity* to resile, not that it actually resile in use. Both options are supported by the common definition of "resilient." *See Merriam-Webster's Collegiate Dictionary* (11th 3d. 2005) 1060 (defining "resilience" as "capable of withstanding shock without permanent deformation or rupture" and "tending to recover from or adjust easily to . . . change").

Though Judge Hubel did not explain what he meant, his opinion indicates that he intended the resilience-in-use interpretation. Referencing the patent specification, he stated "the [invention] would be inoperable as described if it was not formed of a resilient material." *See Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F.3d 1374, 1378 (Fed. Cir. 2006) ("the specification is the single best guide to the meaning of a claim term"). Logically, if resilient material is required for the device to operate as described, then that material must actually

³Claim two reads in relevant part, "[a] method for anchoring in bone a member and attached suture, comprising the steps of: . . . deforming the member in a manner such that the member *resiles* against the portion of the bone that defines the hole. Legaard Decl. in Supp. Pl.'s Markman & Summ. J. Br., Ex. 1 at 10 (emphasis added).

perform its distinct function—resiling. It is inconceivable that the *capacity* for resilience alone is the difference between an effective and ineffective device as described in the patent.

There is also support for the resilience-in-use interpretation in the Federal Circuit's *Ethicon* opinion. Upon review of the district court's various rulings, the Circuit concluded the '557 patent "is directed to an anchor with resilient legs that open and resile after the anchor is pushed into the cancellous bone, lodging the anchor against the cortical layer." *Smith & Nephew, Inc. v. Ethicon, Inc.*, 276 F.3d 1304, 1312 (Fed. Cir. 2001). The Circuit also referenced a statement made by Dr. Hayhurst during the prosecution of '557 where he distinguished his invention from prior art on the basis that '557 encompasses devices that attach to bone through resilience. *Id.* at 1309.

Though framed differently, in its briefing Smith & Nephew raises the doctrine of claim differentiation in opposition to a resilient-in-use interpretation. As between independent claims, the doctrine of claim differentiation acts as a "presumption that each claim in a patent has a different scope." *Curtiss-Wright Flow Control Corp.*, 438 F.3d at 1380 (quoting *Versa Corp. v. Ag-Bag Int'l Ltd.*, 392 F.3d 1325, 1330. In this context, it is a "guide, not a rigid rule." *Id.* at 1381 (internal quotation marks and citation omitted). As a general matter, this doctrine is relevant where a proposed construction renders "additional, or different, language in another independent claim superfluous." *Id.* (internal quotation marks and citation omitted). However, it cannot be used to "broaden claims beyond their correct scope." *Id.* (internal quotation marks and citation omitted).

Smith & Nephew argues the doctrine of claim differentiation is triggered here because interpreting "member" as an anchor that is resilient-in-use renders claim two's specific reference to resiling and claim six and seven's reference to a "deformable member" superfluous. I disagree. As the Federal Circuit explained in *Curtiss-Wright*, "a patentee may define the same subject matter with claims having different terminology." *Id.* at 1381. Thus, even though the resilient-in-use interpretation may diminish the differences between the claims, that fact does not mean

the interpretation is wrong.

Further, I find that the words used in the latter set of claims are not rendered completely superfluous because, when read as a whole, those claims more specifically define the manner in which the resiling must occur than do the more general claims, like claim one. For example, unlike any other claim, claim two specifies "the member [must] resile[] against the portion of the bone that defines the hole." Interpreting "member" as a device that "return[s] to or tend[s] to return to a prior or original position in a manner that contributes, at least in part, to the lodging of the member in the hole" does not render claim two's specific method of resiling meaningless. Likewise, when read as a whole, claims six and seven describe a unique method for accomplishing resilience. And to the extent there is some overlap between "deformable member" and "member" defined as a device that is resilient in use, I conclude this is necessitated by the patentee's formulation of his claims.

Additionally, as Judge Hubel said, it is clear from the patent specification that the distinguishing characteristic of Dr. Hayhurst's invention is that it is a device that resiles in bone. Thus, Smith & Nephew's argument that "member" includes both resilient and non-resilient devices based on the different language used in the various claims would inappropriately broaden the scope of the invention as contemplated by the specification. Whatever Dr. Hayhurst's motivation in including the term "deformable member" in claims six and seven, the claim language cannot be read in a manner that is inconsistent with the overall purpose and function of the invention. *See id.* at 1381 (vacating district court's construction that was inconsistent with "the overall context of th[e] invention and th[e] field of art as described in the specification"). Thus, to conclude, I find the proper interpretation of "resilience," as that term was incorporated into the definition of "member" by Judge Hubel, is that the device must resile in use.

With this understanding of the claim terms, I proceed to the second step of the infringement analysis and consider whether Smith & Nephew has established as a matter of law that Arthrex's devices are resilient and therefore "members" under '557. Smith & Nephew's

argument on this point is that plastic is inherently resilient, and therefore Arthrex's devices, which are made of plastic, are resilient. As stated at the hearing and as is clear from the proceeding discussion, this argument is rejected to the extent Smith & Nephew raises it as a matter of claim construction. Similarly, I find this is an insufficient basis on which to grant summary judgment on this issue of resiliency. Because '557 only covers devices that are resilient-in-use and not just capacity, a more particularized showing of how Arthrex's anchors actually perform is required. This more particularized showing is also necessitated by my construction of "resile," establishing that to come within '557, the resilience must "contribute[], at least in part, to the lodging of the member in the hole." Certainly, it is possible that Arthrex's devices, though made of resilient material, do not perform in a resilient manner, or that even though they do perform resiliently, they do not do so for the *purpose* of lodging the device in bone. The material of which the devices are made simply does not resolve all the issues related to resiliency as defined in '557.

Even if a more particularized showing of how Arthrex's devices actually perform were not required, there is a question of fact regarding the inherent resiliency of plastic. The description of preferred embodiments in '557 suggests Dr. Hayhurst views plastic as an inherently resilient material. Legaard Decl. in Supp. Pl.'s Markman & Summ. J. Br., Ex. 1 at 6, 9 (equating plastic with "resilient material" in description of preferred embodiments).⁴ Likewise, the examiner equated plastic with "resilient material" in a prior related patent application. Pls.' Ex. 15 at 3. However, the relevant prosecution history does not consistently treat plastic as inherently resilient. In the context of a different prior patent application, Dr. Hayhurst distinguished prior art made of plastic on the basis that it was "not resilient." Cho. Decl. in Supp. Markman Br. [Cho Markman Decl.], Ex. W at 11; Cho Decl. in Resp. to Pls.' Markman &

⁴Smith & Nephew's exhibits are identified sequentially regardless of the specific declaration with which they are associated. Therefore, this opinion simply refers to the exhibit number, i.e., "Pls.' Ex. 1."

Summ. J. Br. [Cho Resp. Decl.], Ex. B at 8. Thus, Smith & Nephew's motion for summary judgment on infringement is denied as it has not established as a matter of law that Arthrex's devices are "members" as defined in '557.

B.) Arthrex's Motion

Unlike Smith & Nephew, which had to show Arthrex's devices encompass *all* of the elements of at least one of '557's claims, to prevail on its motion, Arthrex only has to prove that one element is missing. *WMS Gaming, Inc.*, 184 F.3d at 1350. Some of Arthrex's arguments fall away after claim construction. For example, it argued its devices are not "pressed" into bone as described in '557 because they are hammered in place and hammering is not pressing. At the February hearing, I rejected this argument, concluding "'press' means to cause to move by pressure. The type or nature of pressure used is not inherently limited. Thus, 'press' can, though need not always, include hammering or tapping."

Arthrex also asserts it is entitled to summary judgment on infringement because its devices are not resilient in use. Consistent with my resolution of Smith & Nephew's motion on resiliency, I find there are issues of disputed fact for the factfinder to resolve. Arthrex's anchor devices are inserted into a hole in bone smaller than the anchor. Cho Decl. in Supp. Def.'s Mot. Summ. J. Re: Infringement, Ex. J at 4. Arthrex's expert, Dr. Tencer, asserts Arthrex's devices do not infringe '557 because instead of resiling, they are made of a "stiff, non-resilient material" designed to "plow through and then set into bone by impact forces." *Id.* Relying on various testing, Smith & Nephew's expert disagrees, asserting Arthrex's devices actually deform as they pass through the harder cortical bone layer and then resile once in the softer cancellous bone. Pls.' Ex. 20 at 16-17.

Arthrex challenges Smith & Nephew's testing on the basis that it is not direct evidence the accused devices resile in clinical use because the testing was not performed under clinical conditions. However, as Smith & Nephew points out, infringement can be established through circumstantial evidence. *Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 449 F.3d 1209, 1219

(Fed. Cir. 2006). And in spite of any deficiencies in the testing, the fact that Arthrex's devices are inserted into a smaller hole and that they deform as they pass through the cortical bone, creates an inference that this method anticipates some degree of resilience. Additionally, Smith & Nephew contends "the inferences related to Arthrex knowing about the relationship of the various types of bone, the hard cortical bone, the softer cancellus [sic] bone, the relationship of the plastic they chose to use in the anchor, that they chose definitely softer materials than bone that would – that deformed, inherently deform and spring back," is circumstantial evidence that the accused devices resile in use. Tr. at 108. Though this is a close call, I find this evidence is sufficient to create a triable issue of fact and defeat summary judgment as to resiliency. Thus, the remainder of Arthrex's device-specific arguments in support of its motion for summary judgment on non-infringement are addressed below.

1. PEEK SutureTak

Arthrex's PEEK SutureTak device is made of plastic and is one solid piece. There is a hole or passage in the proximal end of the anchor through which the suture is threaded. The only issues raised by Arthrex as relates to this device is whether it is "resilient" as required by Judge Hubel's construction of "member." As discussed above, there is a question of fact regarding whether Arthrex's devices are resilient as that term is understood in this context. Therefore, its motion for summary judgment of non-infringement as relates to this device is denied.

2. Bio-SutureTak

In addition to Arthrex's argument that this device is not "resilient," Arthrex also argues this device fails to meet my construction of "member." At the February hearing, I construed "member" to mean "the anchor itself," and clarified that "[i]t need not be made up of only one piece." The Bio-SutureTak has a ribbed plastic body with an eyelet made from suture thread molded into the proximal end. The suture being anchored is threaded through to eyelet to attach it to the anchor and hold it in the bone. Arthrex argues the molded-in eyelet is not part of "the anchor itself," and therefore the suture threaded through the eyelet is not "attached to" or

"threaded through" the member, as required by '557. I disagree. As previously made clear, the anchor need not be unitary. More importantly, without the eyelet, this device does not function as an anchor because there is no mechanism for connecting the thing being anchored to the plastic body. The plastic body and the suture eyelet must be joined to anchor the suture to the bone. Thus, I find the molded-in eyelet is part of "the anchor itself," and as a result, this device does attach the suture to the member or thread the suture through the member, as described by '557.

Arthrex's motion for non-infringement as to the Bio-SutureTak is denied on the question of "resilience."

3. **Push-Lock**

This device is also made up of two pieces. It has a ribbed plastic body and a separate plastic eyelet that fits inside the distal end of the body. These two pieces are unattached when inserted into the bone hole, but once lodged they are connected with the eyelet resting partially inside the anchor body. Arthrex raises the same issue discussed above concerning whether the eyelet is a part of the anchor, thereby attaching the suture to the anchor. For the same reasons discussed above, I find the eyelet, though a separate piece, is a part of the anchor. Again, without the eyelet, the body of the device could not function as an anchor. Arthrex's motion for non-infringement as to the Push-Lock anchor is denied on the question of "resilience."

4. **V-Tak**

Arthrex's fourth accused device, the V-Tak, is a unitary anchor. Instead of an eyelet or enclosed passage through which the suture is threaded, the V-Tak has a notch or trough formed across the distal end of the anchor body. The suture is laid in the notch and held in place as the anchor is wedged in the bone hole. The pressure from being wedged into the hole is the only thing that keeps the suture connected to the anchor. It is not otherwise tied or fastened to the anchor. Again, the issue is whether this device meets the element of "attaching a suture to a member" or "threading the suture through a passage in the member."

I did not engage in claim construction of the word "attach" on the basis that is a commonly understood term needing no further definition. The dictionary defines it as "to make fast," and gives the examples of "tying or gluing." *Merriam-Webster's Collegiate Dictionary* 79 (11ed. 2005). On the other hand, Smith & Nephew equates "attach" to touching or simple physical contact. It argues that because the V-Tak notch "captures" or holds the suture in place as the anchor is inserted into the bone thereby preventing the suture from changing position or falling out of the bone, the suture and the anchor are "attached." This is inconsistent with the general understanding of this term. Additionally, the patent claims are written as a series of steps. For example, claim one requires:

forming a hole in the bone;
 attaching a suture to a member;
 lodging the member within the hole by pressing the member with attached suture into the hole;
 and attaching tissue to the suture so that the tissue is secured against the bone.

Pls.' Ex. 1 at 10. From the order and language of the these steps, I find this claim anticipates that the suture is attached to the anchor *before* it is inserted into the bone hole. This clearly does not occur with the V-Tak device. Even assuming the suture is "attached" to the anchor due to pressure from the bone wall, before they are inserted into the bone hole, the suture and anchor are simply held together by the physician using the device. They are not attached or made fast to another; they are simply touching. Thus, Arthrex's motion for non-infringement as relates to its V-Tak device is granted on that basis that this device does not encompass the element of "attaching a suture to a member," which, though stated slightly differently, is common to all of '557's claims.

III.) Validity – Anticipation

In answer to Smith & Nephew's complaint, Arthrex asserted several affirmative defenses, including invalidity due to anticipation based on numerous prior art references. Arthrex moves for summary judgment as to only one of those references—*Perthes*. Smith & Nephew cross moves on *Perthes*, as well as numerous other references.

A patent claim is invalid for anticipation if "the invention was patented or described in a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). Each element of the patent claim must be included in a single prior art reference, either expressly or inherently, to invalidate it. *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343 (Fed. Cir. 2005). Further, the court must do a claim-by-claim analysis, only invalidating those claims that are fully encompassed rather than invalidating the whole patent based on the anticipation of one claim. 35 U.S.C. § 282 ("Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims . . ."). Anticipation is a question of fact. *Seachange Int'l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1379 (Fed. Cir. 2005).

A.) Perthes

As explained above, for Arthrex to prevail on its motion it must prove *Perthes* includes each element of '557's claims, whereas Smith & Nephew only has to show one element is missing to prevail on its cross motion. *SmithKline Beecham Corp.*, 403 F.3d at 1343. The primary argument is whether *Perthes* encompasses the steps of "forming a hole in the bone" and "lodging the member within the hole" required in each of '557's claims.⁵

At claim construction, I concluded '557 describes two separate steps where "'forming a hole in the bone' must precede the step of 'lodging the member within the hole.'" (Hearing at 113; Pls.' Markman Br. at 19). I did not construe "hole" as requiring any particular shape or dimension. However, given the wording and order of these steps, the only logical conclusion is that the hole must be sufficient to facilitate lodging of the anchor member. *Perthes* discloses a surgical staple or U-shaped iron nail used to attach tissue to bone. Pls.' Ex. 49 at 17. The staple can either be driven directly through the tissue and the bone, or the surgeon can tether the tissue

⁵The exact wording of these steps varies slightly among the claims, but each of '557's claims encompass the basic steps of forming a hole and lodging the anchor member in the hole.

to the staple head with suture and then drive the staple into the bone. Pls.' Ex. 50 at 10. The references teach that "[i]t is a good idea to use an awl to slightly pre-drill the sites where the nail is to be driven into the [bone]." Pls.' Ex. 50 at 10.

Arthrex argues this slight "pre-drill" equates to '557's "forming a hole in bone." Given that "hole" is not defined, Arthrex's argument is not unreasonable in the abstract. But regardless of whether the pre-drilling creates a "hole," it is clear the pre-drilling is not done for the purpose of lodging the *Perthes* staple within it. Rather, the staple is inserted by driving it directly through the bone, forming a hole in the process, and the pre-drilling is done to help position, or "seat," the staple before it is driven fully into the bone. *See id.* ("Once the nail has seated tightly, it can be driven in . . ."). This is a substantial difference from '557, which does not teach driving the anchor directly into bone, but lodging the anchor into a previously formed hole. Thus, I find *Perthes* does not encompass all the elements of '557's claims. One other distinction as relates to this issue is also worth mention. '557 describes forming only one hole. Throughout the claims, it references "a hole" or "the hole." For the *Perthes* staple to work, there must be two holes formed in the bone. This is also a substantial difference between these two inventions. Thus, Arthrex's motion related to anticipation by *Perthes* is denied, and Smith & Nephew's motion on this issue is granted.

B.) Augustine

The *Augustine* reference discloses a "serrated boat nail" that is "driven into cancellous bone without previously drilling a hole." Pls.' Ex. 64 at 1. In light of the above discussion, Smith & Nephew's motion as to this prior art is granted as it does not encompass "forming a hole," as required in '557.

C.) Burgio

Burgio is a "method for implanting electrodes in or around a human cochlea that involves inserting one end of an anchor in the temporal bone, and functionally engaging a lead to the electrode with the anchor." Pls.' Ex. 56 at 1. Arthrex asserts as an affirmative defense that this

references anticipates '557's claim two. Smith & Nephew moves for summary judgment on this defense, arguing, among other things, that *Burgio* does not encompass claim two's element of "lodging the member within the hole by pressing."

"Lodging" is construed to mean that once the member is pressed into the hole, it "may not be removed." Hubel's Am. F&R at 7. Additionally, "once the member is pressed into the hole, some manipulation may occur, but manipulation beyond pressing must not be necessary in order to secure the member in the hole." *Id.* *Burgio* anticipates removing the anchor described. Pls.' Ex. 56 at 8 (the anchor "may be formed with a rounded tip so that the anchor can be pulled from the socket"). *Burgio* also discusses the need for additional manipulation once the anchor is inserted in the socket to secure it in the socket. Specifically, the reference states:

The first end portion of the anchor is preferably inserted in the socket when the anchor is rotated from its desired orientation (e.g., by about 90 degrees), and the anchor is then rotated to its desired orientation. This will cause the barb to move out of alignment with any groove it formed in the wall defining the socket as it was inserted to thereby enhance its holding power in the bone

Id. at 7. Arthrex's expert, Dr. Burkhead, concluded *Burgio* contains all the elements of claim two, but he did not specifically address "lodging." *See* Pls.' Ex. 48 at 19-20. Likewise, in its briefing in opposition to Smith & Nephew's motion, Arthrex simply stated in reference to this issue: "Claim 2 does not recite that a certain threshold of force is required to remove the anchor from the bone. This is not a valid distinction [between *Burgio* and '557]." Def.'s Mem. in Opp. Pls.' Mot. Summ J. at 20.

Even viewing the evidence in the light most favorable to Arthrex, I find it has failed to meet its burden at summary judgment of showing a genuine issue of triable fact exists for the jury to resolve. *Matsushita Elec. Indus. Co.*, 475 U.S. at 587 (quoting Fed. R. Civ. P. 56(e)) (the non-moving party must set forth "specific facts showing there is a genuine issue for trial"). Dr. Burkhead does not address Smith & Nephew's specific arguments or explain how *Burgio* meets the "lodging" element as it has been defined here. His general conclusion of anticipation, based on an analysis of other elements in claim two, is insufficient. And certainly, counsel's two

sentence response that also fails to address the core of Smith & Nephew's argument is insufficient. Smith & Nephew's motion as to the *Burgio* reference is granted.

D.) McLaughlin

Smith & Nephew argues it is entitled to summary judgment as to whether *McLaughlin* anticipates claims one, four, and five of '557. These claims each include the element of "lodging . . . by pressing." I construed "pressing" as including hammering or tapping, but not screwing. *McLaughlin* discloses a screw passed through bone to repair tendon. Thus, in light of claim construction, this reference does not include the "lodging . . . by pressing" element in the named claims of '557, and Smith & Nephew's motion is granted.

E.) Screw-as-Post Technique

Dr. Hayhurst testified the screw-as-post technique involves inserting a screw in bone, attaching a suture connected to tissue to the screw, and advancing the screw all the way into the bone to affix the tissue to the bone. Pls.' Ex. 60 at 199-201. Smith & Nephew again moves for summary judgment on this reference as relates to claims one, four, and five. For the same reasons discussed in relation to the *McLaughlin* reference, the motion is granted.

F.) Substad

The *Substad* reference discloses a "prosthesis useful in the repair or replacement of damaged or diseased joints in the human body." Pls.' Ex. 62 at 1. The prosthesis is made up of "a shaped body portion adapted to replace a carpal or any other bone or an articular portion thereof" and "a synthetic flexible ligamentous element affixed to said body portion and adapted to tie or affix by tissue invasion to an adjacent tendon, ligament, or bone." *Id.* at 4. One of the preferred embodiments explains the prosthesis body is attached to bone by inserting it into a pre-drilled hole in that bone and suturing it in place. *Id.* at 6.

Smith & Nephew argues this reference does not anticipate '557 because, among other things, it does not encompass the element of "lodging" as defined by Judge Hubel. Just as with the *Burgio* reference, Smith & Nephew argues the need for suturing after the device is pressed or

inserted into the bone means the device is removable upon insertion and further manipulation is required to secure it in place in the bone. Hubel's Am. F&R at 7. Arthrex concedes this device requires suturing to hold it in place, but argues that non-removability is not required by '557. This position fails in light of Judge Hubel's construction adopted here. As cited above, he held that a member is only "lodged" when, "once pressed into the hole, [it] may not be removed." *Id.* There was much discussion at the February hearing about the extent of non-removeability required, but Judge Hubel's opinion clearly establishes that a device that requires further "manipulation beyond pressing" to secure it in place fails to meet this element. Thus, Smith & Nephew's motion as to the *Substad* reference is granted.

G.) Jenkins

The *Jenkins* reference teaches two embodiments raised by the parties' briefing. The first consists of a molded, pointed element attached to fiber strands, where the pointed element guides the strands all the way through the bone hole. Pls.' Ex. 63 at 2, 4. The second embodiment involves a small bone-cement plug that is attached to the end of fiber strands and then inserted into a hole in bone. *Id.*

Smith & Nephew argues the first embodiment does not anticipate '557 because even if the pointed element is a "member," it is not "lodg[ed] . . . within the hole" because it guides the threads all the way through the hole. I agree. Regarding the second embodiment, the parties dispute whether the cement plug is cured before it is placed in the bone hole. Smith & Nephew's expert, Dr. Hayes, concluded the "small plug of bone cement is put in the hole in an uncured or partially-cured state as a putty . . . the small plug of bone cement is lodged by interdigitation by the bone cement within the pores of the bone, and not by pressing." Pls.' Ex. 23 at 49; *see also* Pls.' Ex. 2 at 35 (Dr. Diduch concluding the cement plug is uncured or partially uncured when inserted).

Arthrex asserts the plug is cured when inserted because the *Jenkins* reference states the device can act as a "temporary anchor" after simply being pushed into the hole. Def.'s Mem. in

Opp. Pls.' Mot. Summ. J. at 29. Arthrex takes these words out of context. The relevant passage reads:

[A] small plug of bone cement . . . may be formed around the end of the carbon fibre strand and simply pushed into the formed hole in the bone. This may act as a temporary anchorage until fibrous tissue growth has occurred into the interstices of the carbon fibres.

Pls.' Ex. 63 at 2. In context, I find the words "temporary anchorage" do not establish that the plug is non-removable and therefore "lodged" upon insertion. However, Arthrex is correct that *Jenkins* does not explicitly state whether the cement is cured or not when it is inserted into bone. And without some stated basis from Smith & Nephew's experts for their conclusion that the cement is uncured, I conclude this is not an issue properly resolved at summary judgment. Were there evidence that bone cement is inserted into bone uncured as a matter of medical practice, or some other explanation for why Drs. Hayes and Diduch concluded the cement is uncured when inserted in spite of any such indication in the reference itself, perhaps I could resolve the issue. But, on the current record, I find there is a disputed issue of material fact regarding whether the cement plug is "lodged" when pressed or inserted into the bone. The parties raise additional issues related to this reference, but I find the record is insufficient to resolve those issues at summary judgment as well. Smith & Nephew's motion as to the *Jenkins* reference is denied.

H.) Somers

Smith & Nephew argues *Somers* does not anticipate claim three and that this reference is not prior art because it was filed after Dr. Hayhurst invented claim three. Because I find *Somers* does not encompass all the elements of '557's third claim, I grant Smith & Nephew's motion on that basis without reaching the timing issue.

Like *Augustine*, *Somers* discloses an anchoring device that is inserted directly into bone without forming a hole first. Pls.' Ex. 24 at 1 ("In practice, the surge on [sic] positions the suture anchor drill end on a point on a bone mass in a human body and, by turning the driver, turns the suture anchor to drill into the bone mass."). Arthrex responds that the separate element of

"forming a hole in bone" is encompassed because "it is well-known to pre-drill a pilot hole in a separate step." Def.'s Mem. in Opp. Pls.' Mot. Summ. J. Without some evidentiary support for this assertion, it is insufficient to meet Arthrex's burden at summary judgment. Additionally, the *Somers* device is a screw and therefore this reference also lacks the element of "lodging . . . by pressing." Smith & Nephew's motion is granted as to *Somers*.

I.) *Semple*

The *Semple* reference discloses "[a] bone implant for attaching fibrous connective tissue . . . to bone" comprised of "a tapered porous plug" or "a tendon prosthesis having such a plug at its distal end." Pls.' Ex. 69 at 1. Smith & Nephew's expert, Dr. Hayes, asserts this device is not "lodged" when pressed or inserted into the bone because it is "held in place by 'tension on the plug' and eventual boney in-growth" and "[t]here is no disclosure or suggestion that the plug cannot be removed after placement into the hole." Pls.' Ex. 23 at 72. On the other hand, Arthrex's expert, Dr. Burkhead, concluded the reference teaches "a frustoconical shaped anchor or member designed to be pressed into the bone much like a cork is pressed into a bottle." Cho Decl. in Supp. Def.'s Resp. to Pls.' Mot. Summ. J., Ex. J at 20. On this record, I find there is a question of fact regarding whether the *Semple* device lodges in bone when pressed or inserted therein. As there is no other element challenged by Smith & Nephew that is common to all of '557's claims, I decline to address its remaining arguments at this stage and deny its motion for summary judgment on the *Semple* reference.

J.) *Goble*

Finally, Smith & Nephew argues *Goble* does not anticipate claim three because it does not include the "lodging . . . by pressing" element. It further argues this reference is not prior art based on filing time. Because I find this reference lacks the "lodging" element, I do not address the timing argument.

Goble discloses a two-part device composed of a "suture rivet" and a "slotted ring." Pls.' Ex. 65 at 7. Once inserted into a hole in bone, the pieces are manipulated causing the slotted ring

to expand and secure the anchor in the hole. *Id.* at 10. Clearly, this device is not lodged simply by being pressed into the hole, but rather, further manipulation is required. Arthrex does not respond to this specific issue. *See* Def.'s Mem. in Opp. Pls.' Mot. Summ. J. at 33. Thus, I find there is no genuine issue of material fact to resolve, and I grant Smith & Nephew's motion.

IV.) Invalidity – Obviousness

Arthrex asserts the *Burgio* and *Perthes* references in combination invalidate '557 for obviousness. Smith & Nephew moves for summary judgment on this issue. A patent claim is invalid for obviousness "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103; *Cross Medical Products, Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1321 (Fed. Cir. 2005). Unlike anticipation, obviousness can occur based on a single prior art reference or a combination of references. *Cross Medical Products*, 424 F.3d at 1321. In determining obviousness, the court compares the relevant prior art to the claims of the patent at issue. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966); *see also KSR Int'l Co. v. Teleflex, Inc.*, ___ U.S. ___, 127 S. Ct. 1727, 1739 (2007) (reaffirming *Graham* analysis).⁶

In support of its motion, Smith & Nephew cites two of its experts opining that *Perthes* and *Burgio* in combination do not render '557 obvious and challenging Arthrex's experts' conclusions to the contrary. Dr. Hayes stated a person skilled in the relevant art would not "look to the *Burgio* reference in connection with designing a suture anchor," and in any event, the two references do not encompass many of the elements of '557's claims. Pls'. Ex. 23 at 26-38. In

⁶The parties did not address the *KSR International* decision as it was decided after the briefing and summary judgment hearing, and I find that it is not particularly relevant here. In that decision, the Supreme Court rejected the Federal Circuit's "rigid approach" to the "teaching, suggestion, or motivation" ("TSM") test for obviousness, instead reaffirming the more "expansive and flexible" approach set out in *Graham*. *KSR Int'l Co.*, ___ U.S. at ___, 127 S. Ct. at 1739. Though argued by the parties, for the reasons discussed in the opinion, I find the analysis here does not depend on an application of the TSM test.

doing so, he expressed detailed opinions comparing these references to the elements of '557's claims. *Id.* Likewise, Dr. Diduch stated that Arthrex's experts' opinions are "conclusory, failing to describe how the combination would work or why the combination would be obvious to an orthopedic surgeon." Pls.' Ex. 2 at 25. He also expressed specific opinions explaining that the prior references are lacking several elements of '557's claims. *Id.* at 25-29.

In response to Smith & Nephew's motion, Arthrex does not rely on any evidence other than the prior art references themselves. It does not cite its contrary experts' reports or any other evidence, instead relying primarily on argument. As a general matter, this is an insufficient showing to defeat summary judgment. *Matsushita Elec. Indus. Co.*, 475 U.S. at 587; *see also Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 595 (Fed. Cir. 1997).

Additionally, considering the opinions of Arthrex's experts, as identified by Smith & Nephew, I find summary judgment is appropriate. Dr. Tencer stated that "[i]f 'by pressing' is construed to require a 'constant steady force' . . . , then Perthes and Burgio . . . describe all the steps described in claim 1 (as well as claims 2-7) of the '557 patent. Pls.' Ex. 52 at 6. I rejected this interpretation of "pressing" at claim construction, instead concluding the "type or nature of pressure used is not inherently limited." Thus, the prerequisite for Dr. Tencer's obviousness opinion is missing and this evidence does not create a genuine issue of fact for the jury to resolve. Similarly, Dr. Burkhead concluded *Perthes* and *Burgio* *independently* invalidate '557 because they both disclose all the elements of claim two. He then further opined: "For the reasons previously stated [sic] *Perthes* 1906 in combination with *Burgio* (1982) shows all of the steps of claim 2, thus, in my opinion, invalidating claim 2 in my understanding of the law." Pls.' Ex. 48 at 19-20. As discussed above, I find neither *Perthes* nor *Burgio* invalidate '557 independently. Thus, again, the basis of Dr. Burkhead's opinion has been rejected, also undermining the value of this evidence.

VI.) Double Patenting

Arthrex also asserts '557 is invalid due to double patenting based on three earlier patents

with which Dr. Hayhurst is involved—the '422, '691, and '946 patents. Smith & Nephew moves for summary judgment as to each of these patents. Arthrex cross moves only as to the '422 patent.

The double patenting doctrine prevents a patentee from improperly extending the limited patent monopoly period by getting a second patent for either the same invention or "an 'obvious' modification of the same invention." *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985). Same-invention double patenting is based on 35 U.S.C. § 101, which only allows for one patent per invention. *Id.* In applying this defense, the court considers whether the subject matter, but not necessarily the language used, is identical. *In re Vogel*, 422 F.2d 438, 441 (C.C.P.A. 1970). The test, therefore, is "whether one of the claims could be literally infringed without literally infringing the other. If it could be, the claims do not define identically the same invention." *Id.*

On the other hand, obviousness double patenting is not statutorily based, but is a judicially-created doctrine. *In re Longi*, 759 F.2d at 892. It applies where the claims at issue are different, but where the differences are not "patentably distinct." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed.Cir. 2001). As the Federal Circuit explains, in this context, the court must determine "whether the claimed invention in the [second patent is] obvious from the subject matter of the claims in the first patent, in light of the prior art." *In re Longi*, 759 F.2d at 893. As such, obviousness in this context usually involves some factual considerations, including "what would have been obvious to a person skilled in the art." *Studiengesellschaft Kohle mbH v. N. Petrochemical Co.*, 784 F.2d 351, 355 (Fed. Cir. 1986).

Arthrex asserts its double-patenting defense is based on obviousness. Def.'s Memo. in Opp. Pl.'s Mot. for Summ. J. at 46. However, in arguing this issue it focuses primarily on sameness, contending that the elements of '557's claims are fully encompassed in the earlier patents' claims. *See id.* at 48 ("Each feature of claim 2 of the '557 Patent may be found in claim 25 (which incorporates claim 22 by reference) of the ['422] Patent, with the only difference being slight wording changes."); *see also id.* at 51, 53 (making same argument in relation to '946 and

'691 patents).

As to each of the asserted earlier patents, Smith & Nephew argues they are not the same invention as '557 because they do not encompass the element of "lodging," common to all of '557's claims. Starting with the '422 patent, I find Smith & Nephew is correct. The relevant claims in '422 describe a method for anchoring a suture in bone with a suture anchor using the following steps:

forming a hole in bone;
 inserting [the] suture anchor to a desired depth in the hole in the bone with the tip being inserted first, the trailing portion following said tip, and the suturing thread extending from the hole in the tip and . . . out of the hole in the bone; and
pulling on the portion of suture material extending out of the hole and thereby urging the barb into firmer engagement with the wall of the hole in the bone.

Cho. Decl. in Supp. Def.'s Mot. Summ. J. Re: Double Patenting [Cho Double Patenting Decl.], Ex. B at 6 (emphasis added). "Lodging" in the context of '557 requires that the anchor, "once pressed into the hole, may not be removed." Hubel's Am. F&R at 7. Further, once the anchor is inserted into the bone further manipulation "must not be necessary in order to secure the [anchor] in the hole." *Id.*; *Ethicon, Inc.*, 276 F.3d at 1307. '422's pulling step is inconsistent with this understanding of "lodging" because it *requires* further manipulation beyond simply pressing or inserting the device into the bone hole. Additionally, the claim language makes clear this further manipulation secures the device in the bone. Arthrex does argue that '422's pulling element is consistent with "lodging" as construed under '557. In fact, it does not directly address the pulling element at all, instead focusing on the removability aspect of "lodging." Thus, I find that as to the '422 patent, there is no same-invention double patenting.

Similarly, Smith & Nephew also argues the '691 and '946 patents are also lacking the "lodging" element and therefore are not the same invention as '557. However, unlike the '422 claims, the cited claims in these patents are less explicit on this point. The '691 claims describe an anchor device that is "insert[ed] into a hole of predetermined diameter drilled into a bone"

such that it "fit[s] inside the hole." Cho Resp. Decl., Ex. N at 10. Arthrex baldly asserts this is the same as "lodging." I disagree. As a matter of pure linguistic interpretation, "inserting" contemplates something less than "lodging." "Inserting" refers to placement. Alone, it does not address removeability or the security of the device's placement. In context, one can infer the device must be secured in the bone given that the invention is a suture *anchor*, but there is no indication looking at the claims as a whole that the device is secured once it is inserted into the bone without further manipulation. These claims also do not require that the device "may not be removed" once inserted in the bone.

Likewise, the relevant claim in the '946 patent describes "inserting the suture anchor" into a hole in bone. Again, there is no indication from the wording or the context of the claim that the device is "lodged" into the bone as defined in '557's claims. Thus, I find that these claims also do not cover the same invention as '557, and I grant Smith & Nephew's motion for summary judgment on all of the prior patents as to same-invention double patenting.

As indicated above, Arthrex describes its defense as obviousness-based double patenting. To the extent it argues the differences between '557 and the earlier claims as to "lodging" are not patentable distinctions, I find it has failed to meet its burden at summary judgment. My reading of Federal Circuit authority is that obviousness-based double patenting requires a different analysis than same-invention double patenting. Specifically, to defeat a motion for summary judgment against the defense of obviousness-based double patenting, Arthrex is required to give the court some evidence—some factual presentation—as to why the differences between claims are not "patentably distinct." The analogy, after all, is to the defense of obviousness, which typically requires some testimony as to what one reasonably skilled in the art would have learned from the earlier claim. Here, Arthrex has made no such factual presentation. Instead, it relies solely on argument. While there may be instances where the "patentably distinct" issue is so simple as to not require more than an examination of the claims, this is not such a case. Simply looking at the claim language, I cannot find as a matter of law that these differences are without substance.

"Lodging" is an important aspect of the '557 invention. This is evidenced by the Federal Circuit's opinion stating that devices which require manipulation beyond insertion to secure in bone are not covered by '557. *Ethicon, Inc.*, 276 F.3d at 1310. And Arthrex has not proffered any evidence establishing that the "lodging" element in '557 is an obvious development from the earlier patents. *See Studiengesellschaft Kohle mbH*, 784 F.2d at 355; *see also Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1580 (Fed. Cir. 1991).

Arthrex does make a clear obviousness-based argument as to claim 1 of '557 based on the element of "attaching tissue to the suture so that the tissue is secured against the bone." Def.'s Memo. in Opp. to Pl.'s Mot. Summ. J. at 50. However, because "lodging" is also required in this claim, there is no need to address this issue. Thus, Smith & Nephew's motion for summary judgment as to double patenting is granted as to each of the earlier patents, and Arthrex's cross motion as to the '422 patent is denied.⁷

VII.) Remaining Motions

Smith & Nephew also moves for summary judgment on Arthrex's inequitable conduct defense and invalidity defense based on 35 U.S.C. § 112. As stated at the February hearing, the motion is granted as to inequitable conduct as a result of claim construction. Likewise, claim construction forecloses Arthrex's arguments as to § 112, and Smith & Nephew's motion is granted as to that defense as well. Finally, Smith & Nephew moves for summary judgment as to Arthrex's estoppel defenses. These defenses are resolved by the court's holding that Judge Hubel's claim construction has preclusive effect in this case. Thus, Smith & Nephew's motion on this point is denied as moot.

⁷The parties disagree whether the one-way test or the two-way test for double patenting applies here given the relationship between '557 and the earlier patents. However, because I find '557 is not invalid for double patenting under the one-way test, it is unnecessary to address the two-way test. *In re Berg*, 140 F.3d 1428, 1432 (Fed. Cir. 1998).

VIII.) Conclusion

For the foregoing reasons, Smith & Nephew's motion for summary judgment is granted in part and denied in part. Arthrex's motions for summary judgment as to infringement and prior art are also granted in part and denied in part. Finally, Arthrex's motion for summary judgment as to double patenting is denied.

IT IS SO ORDERED.

DATED this 17th day of May, 2007.

/s/ Michael W. Mosman

MICHAEL W. MOSMAN

United States District Court